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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,591	12/05/2001	Katherine S. Bowdish	1087-3	3521

7590 07/26/2004

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EXAMINER	
LAMBERTSON, DAVID A	
ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/006,591	BOWDISH ET AL.	
	Examiner	Art Unit	
	David A. Lambertson	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,23-37,73 and 74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,23-32,37,73 and 74* is/are rejected.

7)☒ Claim(s) *33-36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed May 7, 2004. Amendments were made to the claims. Specifically, claims 7-22, 38-72 and 75-84 were cancelled.

Claims 1-6, 23-37, 73 and 74 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed January 5, 2004, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6 and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Hornes (as cited in the previous Office Action). **This rejection is maintained for reasons set forth in the previous Office Action.**

As it regards the addition of the limitations whereby the primer and collar sequences are "incorporated into the plasmid," it is argued by the Office that the plasmids used by Hornes necessarily have these sequences "incorporated into the plasmid." If the plasmids did not have

regions of homology with the target nucleic acid sequence, the recombination reaction would not occur because said reaction requires regions of homology between the plasmids and the target. These limitations will be further addressed below in response to the traversal.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 23-32, 37, 73, and 74 are rejected under 35 U.S.C. 102(e) as being anticipated by Zhu (as cited in the previous Office Action). **This rejection is maintained for reasons set forth in the previous Office Action.**

As it regards the addition of the limitations whereby the primer and collar sequences are "incorporated into the plasmid," it is argued that the plasmids used by Zhu necessarily have these sequences "incorporated into the plasmid." If the plasmids did not have regions of homology with the target nucleic acid sequence, the recombination reaction would not occur because said reaction requires regions of homology between the plasmids and the target. These limitations will be further addressed below in response to the traversal.

Response to Arguments Concerning Claim Rejections - 35 USC § 102

Applicant's arguments filed May 7, 2004 have been fully considered but they are not persuasive. The following grounds of traversal are presented with respect to both the rejection in view of Hornes and Zhu:

1. It is argued that Hornes does not disclose or suggest a plasmid having a primer or collar sequence "incorporated into the plasmid" (original emphasis), because "it is not seen where in

the Holmes reference there is any disclosure of modifying a plasmid to arrive at the presently claimed plasmid" (see for example Applicant's response on pages 6-7, bridging and subsequent paragraphs). It is further asserted that Hornes merely discloses that regions of homology can be present "in the target nucleic acid" (original emphasis), but there is no disclosure of incorporating those regions of homology "into the plasmid" (original emphasis).

2. It is argued that Zhu, similarly to Hornes, does not teach a plasmid having a primer and/or collar sequence incorporated into the plasmid. Rather, it is asserted that Zhu teaches incorporating regions of homology into the target nucleic acid so that it may recombine with the plasmid, while not teaching incorporating those same regions of homology into the plasmid (see for example Applicant's response on page 7, the third and fourth paragraphs). This incorporation of primers into the target nucleic acid rather than the plasmid is exemplified by a passage from Zhu (see for example Applicant's response on pages 7-8, the bridging paragraph).

3. It is concluded that, because neither Hornes nor Zhu teach incorporating a region of homology into the plasmid itself, they do not teach the claimed invention. It appears that the argument is based on the method of making the plasmid, whereby a method step for placing the regions of homology between the plasmid and the target nucleic acid into the plasmid is required to anticipate the claimed invention.

Applicant's arguments have been fully considered, but are not found convincing for the following reasons:

1 and 2. The facts are this: the instant claims are directed to a product, specifically a plasmid, and not a method of making or using the plasmid. This plasmid (in its most rudimentary claimed

form) must have three functional elements: a "primer sequence" which has homology to a first portion of a target nucleic acid (which must encode a polypeptide), a "collar sequence" which must have homology to a second portion of the same target nucleic acid, and a restriction site between these first two elements; the issue with regard to the instant rejections focuses on the first and second functional elements of the plasmid, thus the third element will not be addressed further in response to the arguments. It is important to note that there is no specific definition for a "primer sequence" or "collar sequence" set forth in the specification, other than that these sequences must have homology to a given nucleic acid. As such, the terms "primer sequence" and "collar sequence" are reasonably interpreted to be any nucleic acid sequence, so long as the sequence meets the functional limitation of being able to anneal to a given target nucleic acid. Since the invention is a product, the method of making a product in the prior art is irrelevant to the instant claims, and need not be taught by the prior art that is applied. Thus, the issue at hand is whether or not the art teaches a plasmid that meets the limitations of the claimed invention.

Both Hornes and Zhu first teach the production of a nucleic acid that encodes a polypeptide; this is not disputed in the arguments. This nucleic acid is then cloned by recombination into a given plasmid, thus there is a functional requirement that the target nucleic acid encoding the polypeptide and the plasmid contain two regions of homology that are necessary for the recombination to occur; this is not disputed in the arguments. These two regions of homology are structurally and functionally equivalent to the "primer sequences" and "collar sequences" set forth in the instant claims. Thus, both the target nucleic acids and the plasmids taught by Hornes and Zhu comprise the structural and functional equivalents of the "primer sequences" and "collar sequences" set forth in the instant claims. While it is true that

the nucleic acids in both cases are engineered at their 5' and 3' ends with primer sequences having homology to the plasmid, the fact remains that the plasmids used in the teachings of Hornes and Zhu have these regions of homology (i.e., the "primer sequences" and "collar sequences") with the nucleic acid that encodes a polypeptide. Neither Hornes nor Zhu has to teach the engineering of the plasmid to contain these regions of homology because they are already there; if these regions of homology were not present, the recombination reaction would not occur. Thus, Hornes and Zhu necessarily teach plasmids that meet the functional limitations of comprising "primer sequences" and "collar sequences" as defined in the instant claims, because the product meets the structural and functional limitations of the claimed invention.

3. As addressed before, the claimed invention is a product. In order to anticipate the product, the prior art must simply anticipate the structural and functional limitations of the product. It is not necessary to teach a particular method of making the plasmid, or and intended use of the plasmid. The plasmids used in the teachings of Hornes and Zhu have two regions of homology to a nucleic acid which encodes a polypeptide. These two regions of homology are structurally and functionally equivalent to the "primer sequence" and "collar sequence" as set forth in the instant claims. This is regardless of whether or not Hornes and Zhu teach a method step of putting the primer and collar sequences into the plasmid; these sequences are already present in the vector. Thus, the instant claims are anticipated by the plasmids taught in Hornes and Zhu.

In conclusion, the traversal is not found convincing because the argument that a method step for putting the "primer sequence" and "collar sequence" into the claimed plasmids is required to anticipate the claimed invention does not appear to be correct. The product as claimed is structurally and functionally present in the teachings of Hornes and Zhu, as set forth

above. Because the structural and functional limitations of the claimed product are taught, the claimed invention remains anticipated under 35 USC §§ 102(b) and (e).

Allowable Subject Matter

Claims 33-36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.
AU 1636

JAMES KETTER
PRIMARY EXAMINER